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IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

vs.

CIBA-GEIGY CORPORATION,

Respondent.

BRIEF *AMICUS CURIAE* OF THE AMERICAN ASSOCIATION OF RETIRED PERSONS IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

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STATEMENT OF INTEREST

The American Association of Retired Persons ("AARP"), of 1909 K Street, N.W., Washington, D.C. 20049, is a not-for-profit membership corporation of more than 15 million persons over the age of 50. AARP is the largest organized group of older Americans in the country. In representing the interests of its members, AARP seeks to: (a) enhance the quality of life for older persons; (b) promote independence, dignity and purpose for older persons; (c) lead in determining the role and place of older persons in society; (d) sponsor research on physical, psychological, social, economic and other aspects of aging; and (e) represent the point of view of older persons as consumers of goods and services.

In the area of health care, AARP's overriding interest is to foster and promote efficient delivery to older persons of the best possible products and services at the least possible cost, and to make those products and services readily available to persons living within fixed and limited incomes. AARP has steadfastly maintained that elimination of anti-competitive barriers in the drug industry is essential to the achievement of this goal.[1]

REASONS FOR GRANTING THE WRIT

I

THIS CASE PRESENTS IMPORTANT QUESTIONS OF FEDERAL LAW WHICH SHOULD BE SETTLED BY THIS COURT

The social and economic issues raised by this case—including containment of the cost of pharmaceuticals and ensuring that the functional benefits of color-identification of drugs will be

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[1] In support of that goal, AARP has often participated in litigation in this area. For example, AARP submitted an *amicus curiae* brief to this Court in support of generic drug manufacturers in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982). In addition, AARP intervened on behalf of the State of New York in defense of New York's generic drug

available to consumers—are critical to all consumers of drug products, particularly older Americans. In consequence, this case presents important questions of law which should be settled by this Court.

The Anti-Competitive Impact of The Decision Below Will Be Especially Strong Upon Older Americans

AARP's deep concern about the disposition of this petition stems from its involvement with health-related matters affecting older persons and its representation of the consumer interests of older Americans. Due to their advanced age, older Americans depend on regular or frequent administration of pharmaceuticals to maintain their continued health. At the same time, many of those individuals are retired persons who live on low or fixed incomes. Because of the need to contain the already high and rapidly increasing cost of health care, allowing the decision below to remain in effect would be a serious blow to the health and welfare of AARP's fifteen million members and older Americans in general.

The high cost of drugs is particularly onerous to older Americans because Medicare and other insurance often covers only a small portion of that cost. For example, Medicare does not pay for "out-of-hospital prescription drugs." As a consequence, in 1981, older Americans were not reimbursed for 82 percent of the cost of drugs that they purchased. This out-of-pocket ex-

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substitution law, *Pharmaceutical Manufacturer's Association v. Whalen*, 54 N.Y. 2d 486 (1981). Recently, AARP filed a brief in support of a generic drug trade association in an effort to invalidate a Food and Drug Administration policy which works to inhibit the availability of generic drug equivalents. *National Association of Pharmaceutical Manufacturers v. Heckler*, No. 83-4817 (S.D.N.Y., filed June 24, 1983).

AARP has also participated in the legislature process and made its views known to Congress. *See, e.g., Statement on Scientific Literature New Drug Applications Before the Subcommittee on Oversight and Investigation of the House Committee on Energy and Commerce*, 97th Congress, 1st Session (March 10, 1981); *Statement in Support of the Drug Price Competition Act of 1983, H.R. 3605, Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce*, 98th Congress, 1st Session (July 25, 1983).

pense constituted older Americans' fourth largest self-paid health expenditure.[2]

The availability of generic drug equivalents, which usually sell for a fraction of their brand name counterparts,[3] has enabled AARP's members and other consumers to significantly reduce their prescription drug expenditures. AARP believes that the law should not only permit the availability of generic drugs, but should also enable such drugs to compete effectively with brand name products.

For a variety of reasons, brand name manufacturers enjoy a significant advantage in the market for the drugs that they

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[2] *Health Care Financing Administration: Personal Health Care Expenditures Data*, prepared for Senate Aging Committee (Calendar 1981).

HCFA data also shows that persons aged 65 and over, while comprising only 11 percent of the population, incur between 24 and 30 percent of all drug expenditures. On average, an older American will buy prescription drugs 18 times a year, which is two and one half times as often as a person under age 65.

Many older Americans are hard-pressed to keep pace with prescription drug prices, which in 1982 rose by 12 percent according to the Consumer Price Index for All Urban Consumers as reported by the Bureau of Labor Statistics, an increase far in excess of the overall CPI for that year. The United States Census Bureau found that in 1982 the median income of persons 65 and over was 48 percent that of other Americans. *See*, "Money, Income and Poverty Status of Families and Persons in the U.S.: 1982". Report by United States Census Bureau (Series p. 60 No. 140). In 1982, Social Security recipients received a cost of living adjustment of 7.4 percent, 47 Fed. Reg. 20863 (1982), an increase insufficient to cover the increase in drug costs. Older Americans who need prescription medicine and are unable to afford it are often forced to endanger their health either by "stretching" their medication (taking it less frequently than prescribed) or by forgoing certain medicines entirely.

[3] *See, e.g.*, Chemical Marketing Reporter, March 7, 1983, at 14.

One indication of the need for encouraging vigorous competition in the prescription drug industry is the fact that the producer price index for prescription drugs showed an increase of approximately 11% for the third consecutive year in 1983, while at the same time, according to the Bureau of Labor Statistics, the cost of manufacturing prescription drugs declined by 1.1% in 1983.

"Price increases in the prescription area were not linked to any corresponding increase in intermediate cost for pharmaceutical manufacturers. In fact, as measured by the Bureau of Labor Statistics' producer price index for medicinal and botanical chemicals, bulk pharmaceutical material prices declined 1.1% in 1983." Weekly Pharmacy Reports: "The Green Sheet", Jan. 30, 1984 (Citing McKesson's Pharmaceutical Data Services (PDS)).

produce. Securing a patent confers a seventeen year monopoly upon a brand-name drug. During that time, the manufacturer will typically conduct an advertising campaign targeted at physicians. This generally creates a predisposition in favor of the brand-name product among physicians who will write their prescriptions accordingly.[4] In this case, Ciba-Geigy's Apresazide enjoyed a period of five and one half years during which it had no competition from a generic equivalent.

In recognition of the competitive advantage accruing to brand name manufacturers, the legislatures of forty-nine states have adopted so-called "generic drug substitution" statutes which either require or allow the dispensing pharmacist to substitute the generic drug, unless the prescribing physician directs otherwise. These statutes are evidence of the pervasive local interest in fostering effective competition in the pharmaceutical market to achieve some measure of cost containment. The Third Circuit has seriously prejudiced that interest by effectively granting brand-name manufacturers a perpetual monopoly over the color in which the capsules or tablets of their drugs are produced.

The color of drug capsules or pills involves far more than aesthetics; it is a vital competitive characteristic. During the period in which a patent is in effect, brand-name manufacturers typically select a color which becomes identified with the particular drug in the eyes of dispensers such as physicians, hospitals and pharmacists, as well as to patients themselves. After the patent monopoly period expires, the introduction of a generic equivalent capsule in a different color is certain to meet substantial resistance on the part of dispensers and patients alike. Requiring such a different color will therefore foreclose the generic competitor from a substantial portion of the market.

Thus, it is predictable that the Third Circuit's decision, which will severely restrict the ability of generic manufacturers to

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[4] *See, Chemical Marketing Reporter*, March 7, 1983, at 11. ". . . they (physicians) are creatures of habit, like everyone else. If you've been using the same product for 10 to 15 years, you may not necessarily write the prescription in a generic manner." (Quoting Ronald M. Nordmann, Vice President and Senior Drug Analyst for Oppenheimer & Co.).

market their drugs in the same accustomed colors and trade dress used by the brand-name producers, will inhibit competition and inevitably lead to increased prices. This threat to the continued availability of lower-priced, bioequivalent generic drugs, and the absence of downward pressure on prices caused by their competition with brand-name drugs, seriously prejudices older persons—a category of Americans with often the greatest need for drugs, but the most limited means of paying for them.

Consumers Should Not Be Deprived of The Functional Benefits of Color Identification of Drugs

As witnesses below testified, and as this Court noted in its decision in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 853 (1982), the colors used in drug capsules serve important functions.

In the first place, the capsule or tablet color often identifies the therapeutic effect of the medicine to the patient. Since the brand-name product, dressed in the color of the capsule containing it, is the exclusive source of a drug during (and often for some time beyond) its patent life, many patients become accustomed to identifying that drug as "my little blue heart pill."[5] When a bioequivalent generic drug becomes available only in a different color, considerable resistance with respect to the generic alternative may result, event where the patient understands the concept of generic drugs and is aware that generic substitution is being made.[6] This may lead to a lack of patient acceptance of the generic substitute.[7] Such real or perceived patient unwillingness to use the "off-color" generic substitute

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[5] As this Court pointed out in *Inwood*, the District Court there found that "many elderly patients associate color with therapeutic effect." 456 U.S. at 853. In the instant case there is also ample evidence to support this conclusion. *See*, Pet. Br. pp. 7, 18.

[6] *See*, Pet. Br. p. 9.

[7] The District Court acknowledged that "(a) patient who has utilized the brand-name drug over a period of time may accept the generic drug more readily if it looks the same as the brand-name." *Ciba Geigy Corp. v. Bolar Pharmaceutical Co.*, 547 F.Supp. 1095 at 1098 (D.N.J. 1982). Pet. App. p. 9.

may lead physicians to prescribe the brand-name drug to insure that patients will take the necessary medication.

In its opinion, the District Court suggested that patients would overcome their resistance by calling the physician and receiving an explanation.[8] But even if this process would solve the problem in some individual cases, it is likely that instead of devoting their limited time to such telephone calls, physicians would insist that prescriptions be filled with brand-name drugs, especially since they have no personal stake in favoring the use of generic drugs. Thus, concerns about ensuring patient compliance with drug prescriptions may well lead to a decrease in generic substitution, thereby denying many patients access to lower priced generics.[9]

In addition to identifying a medicine's therapeutic value to the patient, after a prolonged period of use the color of a drug becomes part of the patient's routine. Even if a patient eventually accepts a variation in a drug's color, that acceptance may take place only after considerable anxiety and confusion. This may deprive the patient of the important "placebo effect" produced by the drug, i.e., the psychosomatic healing which comes from the patient's confidence and assurance that the medication he is taking will help him.

Another reason why maintaining continuity in the color of drugs is important is that many elderly patients who take multiple medications identify each drug by its color. In fact, where drugs of differing therapuetic effect are comingled in the same container, color becomes the only means of properly identifying each one.[10] Variations in color between brand-name and generic drugs which constitute the same medicine would upset the procedures employed by many older patients to identify or recognize their drugs, and create confusion and possible mistakes in adhering to prescriptions.

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[8] *Id.*, at 1104, Pet. App. p. 22.

[9] The District Court also acknowledged that "[t]he 'look-alike' drug becomes more saleable, because it makes it easier for both the doctor and pharmacist to substitute the generic drug." 547 F Supp. at 1098.

[10] *See, Inwood*, 456 U. S. at 853. *See also*, Pet. Br. pp. 8, 18.

Indeed, the potential for confusion where drugs with the same therapeutic effect have different colors has led hospitals, pharmacies and wholesalers to refuse to purchase generic drugs colored differently from brand-name drugs. As a result of this practice, the availability of lower-cost drugs to older persons has already been impaired.

Finally, uniform drug coloring can save lives by helping to identify the drug involved in overdoses to physicians and emergency personnel acting in life-threatening situations.

Viewed in this social context, the decision below can only have a pernicious impact upon the well-being of older Americans. Simply stated, the courts below chose to ignore or disparage the significant role that drug color plays in the competitive marketplace and the benefits that generic equivalents in the same color as brand-name drugs bestow upon their users. Should the Third Circuit's decision be allowed to stand, it will deal a severe blow to generic drug substitution and to the welfare of millions of consumers and older Americans. For those reasons, the questions of federal law that are raised by the case merit prompt review and definitive determination by this Court.

II

THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISION IN INWOOD AND DECISIONS OF THE SECOND CIRCUIT

As pointed out by petitioner herein (in whose arguments for the granting of certiorari AARP joins), the decision below conflicts with the decision of this Court in the *Inwood* case, and with the decision of the Second Circuit in that case following remand, *Ives Laboratories, Inc. v. Darby Drug Co.*, 697 F.2d 291 (2d Cir. 1982).

Because of the acute social need to foster the availability and use of generic drug substitutes, it is especially important for this Court to resolve those conflicts on such critical legal questions as the proper standards that courts should employ when they

consider the "functionality" and "secondary meaning" of drug color, and to lay to rest any doubt as to its rejection of the "reasonable anticipation" standard for prohibiting the manufacturing of generic drugs with the accustomed appearance of brand-name drugs.

One issue of particular importance to AARP concerns the Third Circuit's application of the law respecting contributory infringement under the Lanham Act. In effect, the courts below restrained Bolar because of the possibility that a few pharmacists might intentionally dispense Bolar's generic product under the guise of the brand-name drug in pursuit of their own economic advantage. The District Court concluded that Bolar had "reason to anticipate the passing off of look-alike product," and speculated that Bolar duplicated Ciba's Apresazide capsule color in order to facilitate such illegal substitution of pharmacists. This reasoning is in clear conflict with the standard adopted by the Second Circuit,[11] and with the governing decisions of this Court.[12]

To guard against the possibility that some pharmacists might illegally substitute generic drugs, the decision below imposed a cure that is worse than the disease. It effectively granted a perpetual monopoly over the color of drug capsules and tablets to brand-name drug manufacturers and, in the process, gave them an unfair advantage over generic competitors. That result is at odds with the policy expressed by the states which have enacted generic substitution laws.[13] It seems self-evident that the social benefits which will accrue from permitting copying of

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[11] In *Ives Laboratories, Inc. v. Darby Drug Co., Inc., et al.*, 601 F.2d 631, 636 (2d Cir., 1979), the Court held that liability would result if the defendant "suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' (the brand-name) mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practice just described." Bolar does not sell or promote its products to pharmacists, so it is difficult to see how it could be liable under this standard.

[12] *See, Inwood*, 456 U.S. at 850 n.13 (1982); *Sony Corp. v. Universal City Studios*, 52 U.S.L.W. 4090, 4095, n.19 (Jan. 17, 1984).

[13] It is also inconsistent with this Court's reasoning that once a product may be legally manufactured by anyone, the original producer does not have an exclusive right to the demand for the product or its goodwill. *See, Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 at 120 (1938).

the color of drug capsules and the facilitation of generic drug substitution would far outweigh any cost from possible illegal passing off of generic drugs as their brand-name counterparts by a few dishonest pharmacists.[14]

AARP had believed that questions relating to the size, shape and color of generic drugs had been settled in favor of duplication of drug trade dress by the *Inwood* decision. As those issues have apparently not been definitively resolved, the Court should resolve them now to protect society's interest in fostering the use of and availability of generic drug substitutes and to enable generic drug firms to serve that interest by formulating their marketing decisions with confidence in the nature of the governing rules.

CONCLUSION

To that extent that generic manufacturers will become unable to compete effectively with the brand-name producers because of the monopoly in capsule color conferred by the Court of Appeals in this case, the brand-name manufacturers will enjoy a restoration of the product monopoly which expired along with their patents. Such a result would be catastrophic for cost containment in the pharmaceutical industry, and would be paid for in large part by older persons—the group of Americans least able to afford it.

Even if generic drug manufacturers manage to remain in the market despite the anti-competitive impact of the decision below, drug identification by color will no longer be possible. As a

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[14] In imputing liability to Bolar, the District Court reasoned that "[t]here are laws against turning back mileage indicators on used cars, not because all dealers do it, but because some have and will", 547 F.Supp. at 1117, Pet. App. p. 49. But laws such as those are aimed at the ones who actually commit the illegal acts. Illegal drug substitution or "passing off" is unlawful and should remain so, and the individuals who commit such acts should be punished. However, otherwise proper conduct should not be proscribed because it could conceivably facilitate illegal conduct by others. In fact, drawing the logical conclusion from the court's analogy would require outlawing the sale of used cars.

result, consumers will be deprived of the functional benefits of color-identification, a burden that once again will fall with particular harshness upon older persons.

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Dated: New York, New York
February 13, 1984

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APPENDIX A

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CONSENT TO FILE BRIEF OF AMICUS CURIAE

Pursuant to the Rules of the Supreme Court of the United States, Rule 36.1, the undersigned counsel for the parties in the above-captioned matter hereby consent to the filing of a brief by the American Association of Retired Persons as Amicus Curiae in support of the Petition for a Writ of Certiorari.

Dated: February 9, 1984

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